Combining Elements of Clinical Effectiveness and Implementation Research Trials: Hybrid Trial Designs

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Outline

- **Brief review of Hybrid Sessions:**
  - **Cyberseminar: October, 2009**
  - **Implementation Workshop: Denver, July, 2010**
- **Audience questions: design challenges**

and/or

- **Exercise in hybrid design**

Why Hybrid Designs?

Hybrid: Something of mixed origin or composition

- **In this case: Effectiveness + Implementation trial components**

Rationale:

- **To speed throughput from clinical evidence to public health impact**
- **To optimize knowledge accrual: "clinical intervention x implementation" interaction effects**

Some Terms Defined

- **Clinical* Intervention: Clinical initiative, manipulation, change to be introduced into a healthcare venue**
  - **e.g.: collaborative care for depression, early aspirin for MI**
- **Implementation Intervention: "A single method or technique to facilitate change" (QUERI Glossary)**
  - **e.g.: automated clinical reminder, performance feedback**
- **Implementation Strategy: "An integrated set, bundle, or package of [implementation] interventions" (QUERI Glossary)**

***Includes *health promotion* and *delivery system* interventions also…**

Clinical Effectiveness Research

- **Effectiveness Research is focused on:**
  - **Follow efficacy research trials**
  - **Health outcomes**
  - **Process measures secondary (e.g.: quality indices, provider behavior)**
  - **Level of analysis typically patient; more recently clinical unit**
  - **Balance of external & internal validity favors external: "real world" settings, larger and more diverse samples**

Implementation Research

- **Implementation Research is focused on:**
  - **Enhancing uptake of established clinical interventions**
  - **Outcomes are usually what clinical trialists consider "process" measures (e.g.: rates of adoption, quality indices)**
  - **Level of analysis typically provider, clinical unit, or facility**
  - **Clinical outcomes data considered not needed since intervention is established (e.g., multiple RCTs in various settings, inclusion in clinical practice guidelines)**

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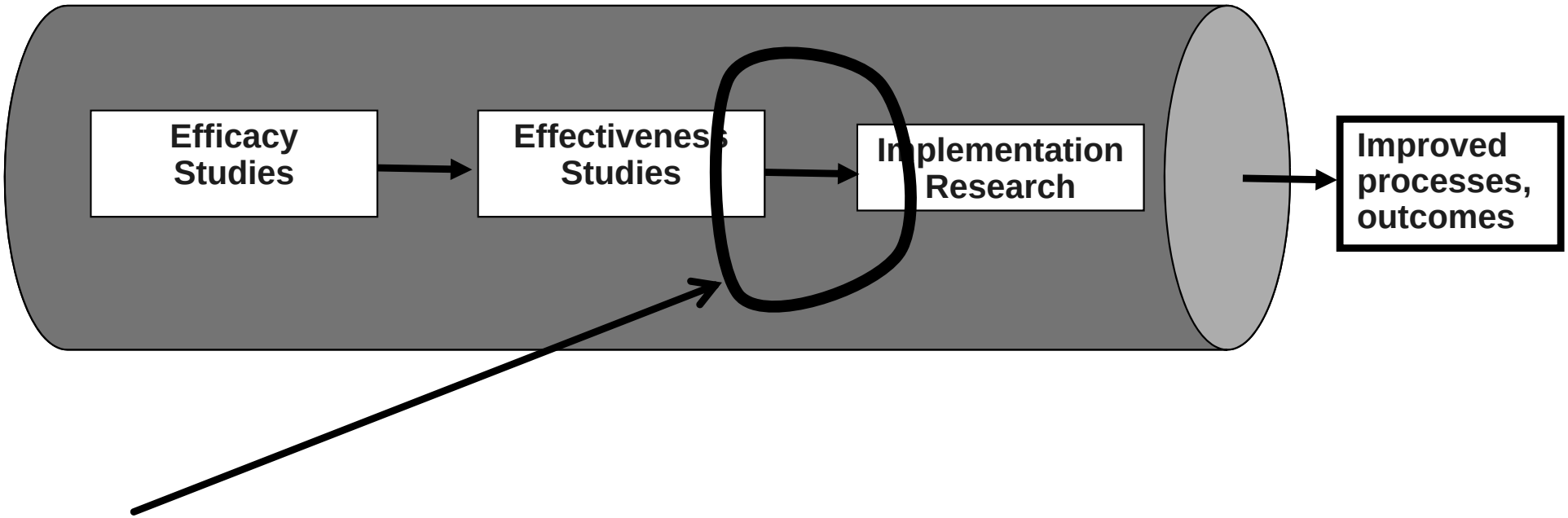
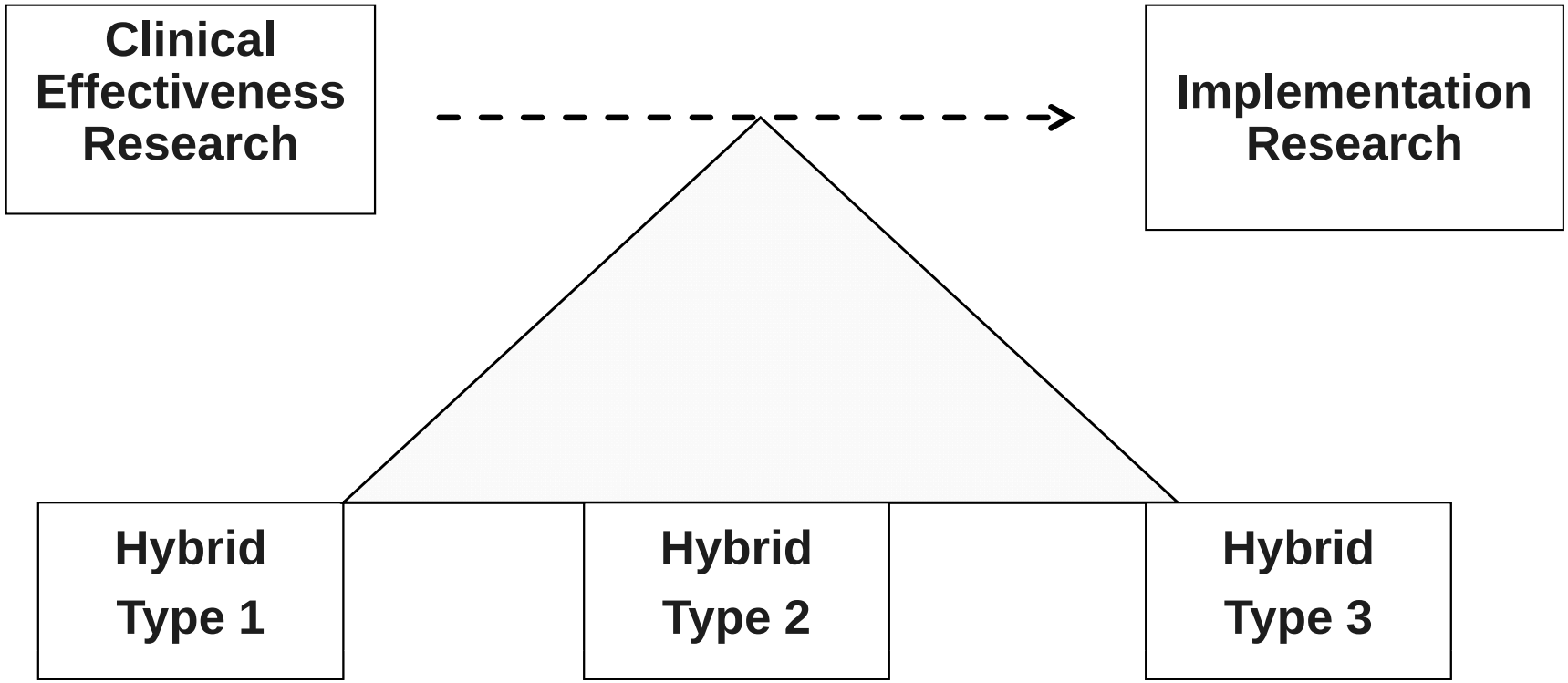
- **The alternative to the fantasy: Endless RCTs of innumerable tweaks for countless specific applications…each followed by an implementation study.**
- **The cost: Long loops; no "interaction" effects**

"Newer" Clinical Research-Implementation Pipeline



***Spatially* speaking, hybrid designs go here…**

First Look at the Types



Hybrid Type 1: test clinical intervention, observe/gather information on implementation

Hybrid Type 2: test clinical intervention, test implementation intervention

Hybrid Type 3: test implementation intervention, observe/gather information on clinical intervention and outcomes

Another Look…

Intervention Focus		Implementation	
		Yes	No
Clinical	Yes	**Hybrid Type II**	**Hybrid Type I**
	No	**Hybrid Type III**	Observational Research

Hybrid Type 1: test clinical intervention, observe/gather information on implementation
Hybrid Type 2: test clinical intervention, test implementation intervention
Hybrid Type 3: test implementation intervention, observe/gather information on clinical intervention and outcomes

(We'll discuss ***randomization*** a bit later…)

More In-Depth: Hybrid Type 1

- **Definition (again):**
  - **Test clinical intervention, observe/gather information on implementation**
- **Description:**
  - **Includes *process evaluations* of implementation during clinical effectiveness trials**
- **Indications:**
  - **Some effectiveness data available, likely to move toward implementation**

More In-Depth: Hybrid Type 3

- **Definition (again):**
  - **Test implementation strategy, observe/gather information on clinical intervention and outcomes**
- **Description:**
  - **Includes *health outcome evaluations* during implementation trials**
- **Indications:**
  - **Robust clinical intervention data available but effects suspected to be “vulnerable” during implementation trial (i.e., most of the time).**

More In-Depth: Hybrid Type 2

- **Definition (again):**
  - **Test clinical intervention & test implementation intervention**
  - **Description:**
    - **Two “sets” of data: clinical (patient- or clinic-level) and implementation (provider-, clinic-, site-level**
- **Indications:**
  - **Robust clinical intervention data available**
  - **Implementation research likely to be preliminary, e.g., feasibility pilot or small-scale efficacy-like trial**

Some Important Questions to Address with Hybrid Designs

- **What intervention or implementation barriers or problems emerge?**
- **What changes to implementation strategy, or clinical intervention, could be made to improve uptake?**
- **Are any parts of the implementation strategy unnecessary?**
- **In what ways are clinical intervention effects sensitive to implementation process factors?**

A Critical Hybrid Component: Evaluating the Trial Process

- **Process Evaluation:**
  - **Identify influences on process of implementation or clinical intervention prior to and/or during study**
  - **No data fed back during study**
  - **Typical of Type 1 designs**
- **Formative Evaluation:**
  - **Identify influences on process of implementation or clinical intervention prior to and during study**
  - **Data used to enhance implementation or clinical intervention processes during study**
  - **Typical of Types 2 & 3 designs**

Some Hybrid Design Considerations

- **Specific research questions / aims**
- **What hybrid *type* will you use?**
- **Randomization or quasi-experimental or both?**
- **System, population, sampling frame**
- **Domains of interest / measures to gather**
- **Unit(s) of analysis**
- **Study duration & tasks:**
  - **Pre-implementation**
  - **Implementation of the clinical intervention**
  - **“Post”-implementation**

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